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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,123	11/09/2005	Steffen Panzner	101215-206	4731

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EXAMINER	
NGUYEN, QUANG	
ART UNIT	**PAPER NUMBER**
1633	

MAIL DATE	DELIVERY MODE
12/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/556,123	PANZNER ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 19-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-6 and 19-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-6 and new claims 19-37 are pending in the present application, and they are subjected to the following restrictions.

Election/Restrictions

Group Restriction

Group I, claims 1-6, 19-25, 35 and 37, drawn to a depot system containing one or more **protein or peptide active substances**, a drug comprising the same depot system and a method for administering the same depot system.

Group II, claims 26-33, drawn to a depot system containing **oligonucleotide active substances**.

Group III, claim 34, a depot system containing one or more water soluble **active substances recited from a Markush group of claim 34, none of which are oligonucelotides nor protein or peptide active substances.**

Group IV, claim 36, drawn to a method of administering a depot system of the present invention comprising the step of one or both from the group consisting of topical and local appliction to support healing processes.

The currently claimed subject matter, Inventions of Groups I-IV, lacks unity of invention according to Rule 13.1 PCT for the following reasons.

The depot systems in Groups I-III are compositions that are different chemically one from the others, as well as each composition has different properties and/or characteristics one from the others. For examples, the depot of Group I contains protein or peptide active substances which are made up of amino acid residues; the

depot system of Group II contains oligonucleotide substances which are composed of nucleotide residues; and the depot system of Group III contain active substances which are neither oligonucleoitdes nor protein nor peptide active substances (e.g., glucocorticoids or small organic molecules that are antibiotic, antimyoctic or cytosatic agents). **Therefore, each of the above compositions does not share the same technical feature, and accordingly the compositions lack the same or corresponding special technical features.** Furthermore, neither the depot system of Group II or Group III is required for the practice of either the first method in Group I or the method in Group IV.

The first method of use in Group I does not share the same technical feature as the method in Group IV because the method in Group I requires specifically the depot system to be injected subcutaneously or intramuscular, while the method in Group IV requires specifically topical and/or local application to support healing processes.

Because the currently claimed subject matter lacks unity according to Rule 13.1 PCT for the reasons set forth above, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Species Restriction

A. ***Should Applicants elect Group I***, this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1. **A single specifically named saturated synthetic phosphatidyl cholines OR a single specific combination of saturated synthetic phosphatidyl cholines** selected from the Markush group recited in claim 1.

2. **A single specifically named cationic lipid** selected from the Markush group recited in claims 1-2 (It is noted that claim 2 is not further limiting claim 1 becasue it recites cationic lipids other than those in the Markush group of claim 1 from which it is dependent on).

3. **A single specifically named protein or peptide active substance** as recited in claims 21-25.

B. ***Should Applicants elect Group II***, this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1. **A single specifically named saturated synthetic phosphatidyl cholines OR a single specific combination of saturated synthetic phosphatidyl cholines** selected from the Markush group recited in claim 1.

2. **A single specifically named cationic lipid** selected from the Markush group recited in claim 1.

3. **A single specifically named oligonucleotide active substance** as recited in claims 21-25 (single strand antisense oligonucelotides; small interfering ds RNA; ds decoy oligonucleotides; aptamers and spieglemers).

C. Should Applicants elect Group III, this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1. **A single specifically named saturated synthetic phosphatidyl cholines OR a single specific combination of saturated synthetic phosphatidyl cholines** selected from the Markush group recited in claim 1.

2. **A single specifically named cationic lipid** selected from the Markush group recited in claims 1-2 (It is noted that claim 2 is not further limiting claim 1 becasue it recites cationic lipids other than those in the Markush group of claim 1 from which it is dependent on).

3. **A single specifically named active substance** as recited in the Markush group of claim 34.

D. Should Applicants elect Group IV, this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1. **A single specifically named saturated synthetic phosphatidyl cholines OR a single specific combination of saturated synthetic phosphatidyl cholines** selected from the Markush group recited in claim 1.

2. **A single specifically named cationic lipid** selected from the Markush group recited in claim 1.

Applicant is required, in reply to this action, **to elect a single species consistent to the elected invention** to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reason:

Each of the aforementioned species is different structurally one from the others. **Each different structure can be considered to be a "special technical feature"; and therefore the listed species lack the same or corresponding special technical features.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent

Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

QUANG NGUYEN, PH.D.
PRIMARY EXAMINER